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(54) **Resorbable tendon and bone augmentation device**

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Description

This invention relates to a device implantable in the living body for attachment and augmentation of tendons and/or reinforcements of bones as specified in the preamble of Claim 1. Such a device is known from DE-U-9 002 844.

The device according to the invention is particularly useful for the attachment and augmentation of the disrupted tendons of the rotator cuffs and the reinforcement of the proximal humeral bone.

Disorders of the rotator cuff are the most common cause of painful shoulder disability. The natural history of untreated ruptures of the rotator cuff are much less favourable than previously thought. Attempts of surgical repair of ruptures almost consistently yield satisfactory pain relief, in contrast to functional restoration which is less certain, particularly in large tears. This has been attributed to a variety of factors:

- the quality of muscle motoring the tendon may be irrevocably poor;
- the quality of the tendon (circulation, elasticity, tensile strength) may preclude repair;
- the quality of cancellous bone may not provide enough stability (e.g. in the case of osteoporosis); or
- the patients cooperation may defeat the surgical gaol.

It has been established, that functional restoration of the shoulder does not depend on the cuff rotator tear size, but on the success of repair of the defect. Thus the anatomical and mechanical success of operative tendon-to-bone attachment is therefore of great importance.

Several factors, which influence the quality of repair such as the suture material, the quality of initial fixation, the tension in the musculotendinous unit and the load applied during the postoperative course influence the success of the repair. One of the important problems is how to grasp the tendon with the suture material to achieve a strong and secure attachment of the tendon to the bone.

Very few literature data concerning this problem are available and yet refer to the surgical attachment of the supraspinatus tendon, e.g. as described in an article of France, Paulos, Harner and Straight "Biomechanical evaluation of rotator cuff fixation methods" published in Am J Sports Med 17:176-181,1989.

Different prior art methods of soft tissue-to-bone fixation have been evaluated, e.g. fixation to bone by spiked washers and screws, using spiked soft tissue plates, different kinds of staples and suturing. It has been found that independently on the suturing technique used, the suture material pulls through the tendon.

It has been also observed that when using prior art non-augmented techniques for the tendon-to-bone attachment

[e.g. according to the Kessler technique described in ML Mason, HS Allen, "The rate of healing of tendons. An experimental study of tensile strength", Ann Surg 113-3, 424-59(1941);
AD Forward, J Cowan, "Tendon suture to bone", J Bone Joint Surg 45-A(4), 807-823(1963); and
LD Ketchum, NL Martin, DA Kappel, "Experimental evaluation of factors affecting the strength of tendon repairs", Plast Reconstr Surg 59(5), 708-719-(1977)]

there is a diastasis formed between connected elements, while suture applied to the tendon strangulates and/or pulls out the tendinous tissue.

Attempts have been made (France, Paulos, Harner and Straight "Biomechanical evaluation of rotator cuff fixation methods" published in Am J Sports Med 17:176-181,1989) to strengthen tendon-suture interface by interposing a polytetrafluoroethylene (PTFE) membrane between suture and tendon. Although it was expected that the membrane will augment the holding power of the tendon, no significant improvement was observed.

In addition it was observed in reoperations that shoulder function is usually not achieved, because of diastasis between the tendon and bone. While the suture material stays always intact, the tendon is connected to the bone through functionally insufficient scar tissue.

From J.R.Parsons, H. Alexander, S.F. Corcoran and A.B. Weiss "Development of a variable stiffness, absorbable bone plate", 25th Annual ORS, San Francisco, California, February 20-22, 1979 a bone plate is known consisting of a resorbable polymeric matrix reinforced with non-resorbable carbon fibres. The disadvantage of this known bone plate is therefore its limited resorbability due to the non-resorbable carbon fibres present in the polymeric matrix. The pure polymeric matrix of this known device without the reinforcing non-resorbable carbon fibres would have an unacceptable low tensile strength whereas the reinforced bone plate has an unacceptable high Young's modulus.

From DE-U-9 002 844 a button-like osteosynthetic device made from PDS (a registered trade mark) of undefined quality is disclosed as suture fixation. The disadvantage of this device lies in the lack of suitable materials specifications which are necessary for obtaining good clinical results.

The same disadvantage relates to the resorbable prosthesis known from WO88/06872.

Finally a biocomposite material is known from WO88/03417 for bone surgical applications which comprises at least one non-degradable bioceramic component. As the bioceramic component is not resorbable this material is not useful for the in-

tended purpose.

The invention as claimed is intended to remedy these drawbacks. It solves the problem of how to design a device implantable in the living body for attachment and augmentation of tendons and reinforcement of bones having a superior tensile strength of the tendon repair and/or allowing a more secure fixation of transosseous sutures.

The invention solves the problem with a device comprising the features of claim 1.

The device according to the invention comprises a substantially flat membrane having a rounded outer shape and at least two perforations.

The membrane contains only resorbable or degradable polymeric material having a Young's modulus in the range of 1 to 50 GPa and a tensile strength in the range of 0.1 to 20.0 GPa and preferably of non-porous structure. The membrane may contain additionally resorbable or degradable polymeric-ceramic material. The advantage of this addition being an enhanced biocompatibility of the membrane.

Young's modulus is preferably in the range of 5 to 15 GPa and most preferably in the range of 7 to 10 GPa. Tensile strength is preferably in the range of 0.5 to 3.0 GPa and most preferably in the range of 0.7 to 2.5 GPa.

Resorbable materials to be used for the device according to the invention are resorbable polymers like highly purified polyhydroxyacids, polysaccharides, polyamines, polyaminoacids, polyorthoesters, polyanhydrides, polyamidoesters, polydioxanone, polyesteramides, copolyoxalates, polycarbonates or poly(glutamic-co-leucine). Preferably polylactides are used or their combinations with polyhydroxybutyrates or polyhydroxyvalerates and/or resorbable glasses.

Other useful polyhydroxyacids comprise polycaprolactone, poly(L-lactide), poly(DL-lactide), polyglycolide, poly(DL-lactide-co-glycolide), poly(DL-lactide-co-caprolactone).

At least 90 weight percent of the resorbable polymeric material should have a molecular weight in the range of 200,000 to 400,000, preferably in range of 300,000 to 350,000.

In terms of molecular weight distribution the polymeric and/or polymeric-ceramic material has a polydispersity (as defined in "Textbook of Polymer Science" 3rd edition, Billmeyer, Wiley-Interscience) in the range of 1.2 to 100.0, preferably in the range of 1.5 to 3.0.

The resorbability of said material should be set at a level allowing to maintain adequate mechanical properties in vivo for at least 6 months, and preferably 7 months. The resorption rate can be adjusted to a desired value by altering the polymer molecular weight, the polymer chain orientation and crystallinity, physical structure, chemical composition, presence and extent of voids, additives a.s.o.

By way of example poly(L-dL lactide) with 5% of dL-units and a molecular weight of 400.000 Daltons resorbs at the rate which assures augmentation during the healing time. Another example for a suitably resorbable material which maintains the required mechanical properties till the healing is complete is poly(L-lactide) with a molecular weight of 320.000 Daltons hot drawn to draw ratio 4. Still another example is poly(L-lactide) with a porosity in the range of 0.1 to 0.5 μm and a molecular weight of 300.000 Daltons which maintains 70% of its initial tensile strength 6 months after implantation.

The resorbable materials to be used with the invention should preferably be of non-porous structure to avoid tissue ingrowth, which would interfere with the gliding function of the tendon.

The resorbable polymeric tendon and/or bone augmentation device according to the invention can be produced either from a thin nonporous film, membrane or plate or likewise from a film, membrane or plate with controlled porosity and in vivo resorption time.

The thickness of the membrane can be controlled to meet structural demands of the proposed implantation site, but should range between 0.5 and 6.0 mm, preferably between 1.0 and 2.0 mm and most preferably between 1.4 and 1.5 mm.

Preferably the surface of the membrane which faces the tendon is provided with spikes to prevent slippage of the device on the tendon. Instead of spikes it is possible to use any suitable irregularities or corrugations on said surface of the membrane to obtain the same effect.

The augmentation device according to the invention can also be used as a drug delivery device, containing antibiotics and/or fibroblast growth factor.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming part of this disclosure. For the better understanding of the invention, its operating advantages and specific objects attained by its use, reference should be had to the accompanying drawings, examples and descriptive matter in which are illustrated and described preferred embodiments of the invention.

Fig. 1 is an elevational view of a tendon augmentation device according to the invention having a longitudinal shape with sectional views at locations A-A, B-B, C-C and D-D;

Fig. 2a is an elevational view of a device according to the invention having a circular shape;

Fig. 2b is a section through the device according to Fig. 2a;

Fig. 2c is a perspective view of the device according to Figs. 2a and 2b;

Fig. 3 is a perspective view of the tendon augmentation device according to Fig. 1 applied on a tendon;

Fig. 4 is a perspective view of a pair of tendon augmentation devices according to Figs. 2 applied on a tendon;

Fig. 5 is an elevational view of a bone augmentation device according to the invention having a longitudinal shape with sectional views at locations A-A, B-B, C-C and D-D; and

Fig. 6 is a perspective view of a drilling jig for effecting of the necessary bone perforations.

Fig. 1 shows a device according to the invention consisting of a substantially flat membrane 1 having a rounded outer shape, with the approximate dimensions of 5.0 x 10.0 x 1.4 mm, having two pairs of lateral holes 2,3 and 4,5 with diameters in the range of 0.2 to 2.5 mm, and preferably 1 mm, to house the suture. All edges of the device are rounded to prevent irritation of the tissue and diminish the chance of suture damage due to friction. The surface 6 of the device which faces the tendon has 0.5 mm long spikes 7 to prevent slippage of the device on the tendon. The opposite surface 8 of the flat membrane 1 of the device is strengthened by incorporation of three bars 9 of the same material as the membrane 1.

Figs. 2a, 2b and 2c show a tendon augmentation device according to the invention which has a circular shape in the form of a disk 10. The diameter of the disk 10 is about 8 mm and its thickness about 2 mm. The disk 10 has two or three 0.5 mm thick reinforcing bars 11 of the same material as the disk to support the suture and two holes 12 with a diameter of 0.5 to 1.3 mm to house the suture and two cuts 13 at the edges of disk 10 to protect against slippage of the suture over the device. The surface 14 of the device facing the tendon has rounded edges 15 to diminish irritation and 0.5 to 1.0 mm long spikes 16 to prevent slippage of the device on the tendon.

As illustrated in Fig. 3 the tendon augmentation device 1 according to Fig. 1 is used for repairing and augmenting a disrupted tendon in a living body. The surgical method comprises the following steps:

A. Placing the augmentation device 1 intraoperatively on the surface 17 of the tendon 18.

B. Pulling proximally, along the tendon direction, the suture 19 from the cut end of tendon 18, towards its outer surface.

C. Pulling the suture 19 through the tendon 18 and one pair of two lateral holes 3,2 and towards the outer surface of the tendon 18.

D. Pulling the suture 19 back through the tendon 18 and the other pair of lateral holes 4,5 towards its outer surface.

E. Pulling the suture 19 longitudinally through the tendon 18 to its distal cut end.

Once fixed to the tendon the membrane 1 prevents the suture 19 from cutting through the tendon 18 at the point of highest stress (pulley).

The same operative technique is illustrated in Fig. 4 when a pair of disk-shaped devices 10 according to Fig. 2 are used. The operative method comprises:

A. Placing a first device 10 according to claim 5 on the surface 17 of the tendon 18.

B. Pulling proximally, along the tendon direction, a suture 19 from the cut end 20 of tendon 18 towards the device 10 and through one of its holes 12 to its outer surface.

C. Pulling the suture 19 through one of the cuts 13 into the tendon 18 towards to outer surface of the tendon 18.

D. Pulling the suture 19 back into the tendon 18 through the other cut 13 and the other hole 12 and again into the tendon 18.

E. Pulling the suture 19 longitudinally through the tendon 18 to its distal cut end.

F. Placing a second device 10 according to claim 5 on the surface 17 of the tendon 18 and performing steps B to E.

In vitro tests showed that the use of resorbable tendon augmentation devices according to the invention for the augmentation of the supraspinatus tendon, increased the pull out strength up to 469 N (126%), as compared with the nonaugmented suture technique (with a tensile strength of 371 N only).

Fig. 5 shows a bone augmentation device consisting of a membrane 20 similar to the one used for the tendon augmentation device according to Fig. 1. It is fashioned into a rectangle, preferably with dimensions of 5.0 x 10.0 x 1.4 mm, with rounded edges to prevent irritation of the surrounding tissue and diminish friction between the suture and the device. The membrane 20 has two holes 21,22 and three reinforcing bars 23.

Intraoperatively the device according to Fig. 5 is placed onto the osteoporotic bone of e.g. the humeral head. The suture is pulled through the holes 21,22 while the device acts as a washer. In vivo tests in the sheep with the resorbable device according to Fig. 5 to augment the bone showed to increase its holding power to 398 N (520%), as compared with 76 N for the nonaugmented cancellous bone. It allows therefore a more secure fixation of transosseous sutures to the bone.

A similar surgical technique is used for the bone augmentation device but care should be taken that the holes drilled into the bone have identical distances between them as in the device to be secured to it in order to prevent cutting the bone by the suture material and diastasis which can be

formed when the bone is cut. To achieve a high accuracy which is desirable it is recommended to use a special drill guide 22 as shown in Fig. 6 with guiding holes 21 corresponding exactly to the holes 12 of the device 10 to be secured to the bone.

The use of both, the tendon and the bone augmentation devices according to the invention have several advantages as compared with existing repair techniques. Thus, it reduces diastasis between the tendon and the bone being the main problem in the rotator cuff tear repair, it protects against tendon strangulation and cutting through the tendon and the osteoporotic bone at the place of fixation. The use of resorbable augmentation devices according to the invention has also additional advantages, i.e. once the device is resorbed, it no longer affects the already critical blood supply.

The tendon and bone augmentation device according to the invention can be prepared using one of the common techniques applied to polymer processing, e.g. injection-moulding, extrusion, compression-molding, solution-casting, etc.
The devices can be produced as a composite device consisting of a resorbable polymer reinforced with resorbable polymeric fibres.

Examples for manufacture:

I. A nonporous membrane with dimensions of 5.0 x 10.0 x 1.4 mm was prepared by casting from 10 wt.-% solution of poly(L-lactide) in chloroform at room temperature. Poly(L-lactide) with viscosity-average molecular weight of 350.000 Daltons used for preparation of the membrane was purified twice by dissolution in chloroform followed by precipitation with a methanol/water mixture. Membranes were dried to constant weight in vacuum oven at 70°. Augmentation devices of the required size were cut out from the membranes using a steel stamp. When used to augment the supraspinatus tendon they increased the pull out strength of the tendon to 470 N as compared with 370 N for nonaugmented tendons.

II. A nonporous membrane with dimensions of 5.0 x 10.0 x 0.7 mm was prepared by casting from 7 weight-percent solution of poly(L-lactide) with a viscosity-average molecular weight of 350.000 Daltons in chloroform. When used to augment osteoporotic bone it increased the holding strength of the bone from 70 N to 270 N.

III. A nonporous membrane with dimensions of 5.0 x 10.0 x 1.4 mm was prepared by injection molding of highly purified poly(L-lactide) with a viscosity-average molecular weight of 340.000 Daltons. The polymer was dried and kept under vacuum prior to injection-moulding to diminish thermomechanical degradation. The augmentation device placed on osteoporotic bone of the humeral head increased the holding strength of the bone from 75 N to 400 N.

IV. A porous membrane with porosity in the range in the range of 0.5 to 1.0 μm and dimensions of 5.0 x 10.0 x 2.0 mm was prepared by solution casting from poly(L-lactide) with molecular weight of 240.000 Daltons. The augmentation device was cut out from the membrane using a steel stamp with a suitable shape. Reinforcing bars pressed in the microporous device using a suitable mould/hydraulic press system. The augmentation device placed on osteoporotic bone of the humeral head increased the holding strength of the bone from 80 to 310 N.

V. Several manufacturing processes can be used to include reinforcing bars into the augmentation devices:

a) Injection molding:
The mould used for preparation of the augmentation device has a shape which allows formation of the reinforcing bars in one injection-molding operation;

b) Extrusion:
The polymer ribbon is extruded through a nozzle having a shape of a device with the reinforcing bars. The final device is cut out from the ribbon using a suitable stamp.

c) Solution casting:
A membrane is prepared by solution casting. Next the membrane is placed in a mould with a suitable shape and subsequently compression moulded at temperatures in the range of 80° to 110°C.

Claims

1. A device implantable in the living body for attachment and augmentation of tendons and/or reinforcement of bones, comprising a substantially flat membrane (1;10,20) having a rounded outer shape, a tendon/bone facing surface and at least two perforations (2,3;4,5;12;21,22), said device containing only resorbable or degradable polymeric material selected from the group consisting of polyhydroxyacids, polysaccharides, polyamines, polyaminoacids, polyorthoesters, polyanhydrides, polyamidoesters, polydioxanones, polyesteramides, copolyoxalates, polycarbonates or poly(glutamic-co-leucine),
characterized in that
A) said polymeric material is of a highly purified quality;

B) said polymeric material has a Young's modulus in the range of 1 to 50 GPa;
C) said polymeric material has a tensile strength in the range of 0.1 to 20.0 GPa;
D) at least 90 weight percent of said polymeric material has a molecular weight in the range of 200,000 to 400,000;
E) said polymeric material has a polydispersity in the range of 1.2 to 100.0; and
F) the polymeric chains in said polymeric material are at least partially oriented.

2. A device according to claim 1, wherein said membrane additionally contains resorbable or degradable polymeric-ceramic material.

3. A device according to claim 1 or 2, wherein said resorbable or degradable polymeric material and/or said polymeric-ceramic material is of nonporous structure.

4. A device according claim 1 or 2, wherein said resorbable or degradable polymeric material and/or said polymeric-ceramic material is of porous structure with controlled porosity in the range of 0.05 to 200 µm, preferably in the range of 0.2 to 5.0 µm.

5. A device according to one of the claims 1 to 4, wherein said membrane has a circular outer shape.

6. A device according to one of the claims 1 to 4, wherein said membrane has the shape of a tape with rounded ends with at least two perforations at each of the two ends.

7. A device according to one of the claims 1 to 6, wherein said membrane is deformable to the shape of a bone.

8. A device according to one of the claims 1 to 7, wherein the thickness of said membrane is between 0.5 and 6.0 mm.

9. A device according to claim 8, wherein the thickness of said membrane is between 1.0 and 2.0 mm, preferably between 1.4 and 1.5 mm.

10. A device according to one of the claims 1 to 9, wherein said Young's modulus is in the range of 5 to 15 GPa, preferably in the range of 7 to 10 GPa.

11. A device according to one of the claims 1 to 10, wherein said tensile strength is in the range of 0.5 to 3.0 GPa, preferably in the range of 0.7 to 2.5 GPa.

12. A device according to one of the claims 1 to 11, wherein at least 90 weight percent of said polymeric material has a molecular weight in the range of 300,000 to 350'000.

13. A device according to one of the claims 1 to 12, wherein said polymeric material has a polydispersity in the range of 1.5 to 3.0.

14. A device according to one of the claims 1 to 13, wherein said polyhydroxyacids comprise polycaprolactone, poly(L-lactide), poly(DL-lactide), polyglycolide, poly(DL-lactide-co-glycolide), poly(DL-lactide-co-caprolactone).

15. A device according to one of the claims 1 to 14, wherein a fibroblast activating agent is incorporated in the polymeric matrix.

16. A device according to one of the claims 1 to 14, wherein an osteoplastic agent is incorporated in the polymeric matrix.

17. A device according to one of the claims 1 to 14, wherein an antibiotic agent is incorporated in the polymeric matrix.

18. A device according to one of the claims 1 to 17, wherein the polymeric material has a degradation rate in situ in the range of 6 to 24 months.

19. A device according to one of the claims 1 to 18, wherein said membrane is preshaped to conform to the curvature of the humeral head.

20. A device according to one of the claims 1 to 19, wherein a surface (14) of said membrane facing the tendon and/or bone is provided with a three-dimensional structure, preferably in the form of spikes (16), corrugations or irregularities.

21. A device according to one of the claims 1 to 20, wherein a surface (14) of said membrane facing the tendon is provided with rounded edges (15).

Patentansprüche

1. Vorrichtung, die zur Befestigung und Augmentation von Sehnen und/oder zur Verstärkung von Knochen in den lebenden Körper implantiert werden kann und aus einer im wesentlichen flachen Membran (1;10,20) mit abgerundeter Außenform, einer zur Sehne/zum Kno-

chen hin liegenden Fläche und wenigstens zwei Perforationen (2,3;4,5;12;21,22) besteht, wobei die Vorrichtung ausschließlich aus absorptionsfähigem oder abbaubarem Polymermaterial besteht, das aus der Gruppe der Polyhydroxysäuren, Polysaccharide, Polyamine, Polyaminosäuren, Polyorthoester, Polyanhydride, Polyamidoester, Polydioxanone, Polyesteramide, Kopolyoxalate, Polykarbonate oder Poly(glutamic-co-Leukine) ausgewählt wird, dadurch gekennzeichnet,

A) daß das Polymermaterial hochrein ist;

B) daß das Polymermaterial ein Elastizitätsmodul zwischen 1 und 50 GPa aufweist;

C) daß das Polymermaterial eine Reißfestigkeit zwischen 0,1 und 20,0 GPa aufweist;

D) daß wenigstens 90 Gewichtsprozent des Polymermaterials ein Molekulargewicht zwischen 200.000 und 400.000 aufweisen;

E) daß das Polymermaterial eine Polydispersität zwischen 1,2 und 100,0 aufweist und

F) daß die Polymerketten in dem Polymermaterial wenigstens teilweise ausgerichtet sind.

2. Vorrichtung gemäß Anspruch 1, wobei die Membran zusätzlich ein absorptionsfähiges oder abbaubares polymerkeramisches Material enthält.

3. Vorrichtung gemäß Anspruch 1 oder 2, wobei das absorptionsfähige oder abbaubare Polymermaterial und/oder das polymerkeramische Material eine nicht poröse Struktur aufweist.

4. Vorrichtung gemäß Anspruch 1 oder 2, wobei das absorptionsfähige oder abbaubare Polymermaterial und/oder das polymerkeramische Material eine poröse Struktur und eine kontrollierbare Porosität zwischen 0,05 und 200 µm, vorzugsweise zwischen 0,2 und 5,0 µm aufweist.

5. Vorrichtung gemäß einem der Ansprüche 1 bis 4, wobei die Membran eine kreisförmige Außenform besitzt.

6. Vorrichtung gemäß einem der Ansprüche 1 bis 4, wobei die Membran die Form eines Bandes mit abgerundeten Enden sowie wenigstens zwei Perforationen an jedem der beiden Enden aufweist.

7. Vorrichtung gemäß einem der Ansprüche 1 bis 6, wobei die Membran an einen Knochen angeformt werden kann.

8. Vorrichtung gemäß einem der Ansprüche 1 bis 7, wobei die Dicke der Membran zwischen 0,5 und 6,0 mm liegt.

9. Vorrichtung gemäß Anspruch 8, wobei die Dikke der Membran zwischen 1,0 und 2,0 mm liegt, vorzugsweise zwischen 1,4 und 1,5 mm.

10. Vorrichtung gemäß einem der Ansprüche 1 bis 9, wobei das Elastizitätsmodul zwischen 5 und 15 GPa liegt, vorzugsweise zwischen 7 und 10 GPa.

11. Vorrichtung gemäß einem der Ansprüche 1 bis 10, wobei die Reißfestigkeit zwischen 0,5 und 3,0 GPa liegt, vorzugsweise zwischen 0,7 und 2,5 GPa.

12. Vorrichtung gemäß einem der Ansprüche 1 bis 11, wobei wenigstens 90 Gewichtsprozent des Polymermaterials ein Molekulargewicht zwischen 300.000 und 350.000 aufweisen.

13. Vorrichtung gemäß einem der Ansprüche 1 bis 12, wobei das Polymermaterial eine Polydispersität zwischen 1,5 und 3,0 aufweist.

14. Vorrichtung gemäß einem der Ansprüche 1 bis 13, wobei die Polyhydroxysäuren unter Polycaprolakton, Poly(L-Laktid), Poly(DL-Laktid), Polyglykolid, Poly(DL-Laktid-co-Glykolid) und Poly-(DL-Laktid-co-Caprolakton) ausgewählt werden.

15. Vorrichtung gemäß einem der Ansprüche 1 bis 14, wobei ein fibroblast-aktivierendes Mittel in die Polymermatrix eingelassen wird.

16. Vorrichtung gemäß einem der Ansprüche 1 bis 14, wobei ein osteoplastisches Mittel in die Polymermatrix eingelassen wird.

17. Vorrichtung gemäß einem der Ansprüche 1 bis 14, wobei ein Antibiotikum in die Polymermatrix eingelassen wird.

18. Vorrichtung gemäß einem der Ansprüche 1 bis 17, wobei das Polymermaterial eine In-situ-Abbaurate zwischen 6 und 24 Monaten aufweist.

19. Vorrichtung gemäß einem der Ansprüche 1 bis 18, wobei die Membran vorgeformt wird, um sich der Biegung des Oberarmbeins anzupassen.

20. Vorrichtung gemäß einem der Ansprüche 1 bis 19, wobei eine zur Sehne und/oder zum Knochen hin liegende Fläche (14) der Membran

eine dreidimensionale Struktur aufweist, vorzugsweise in Form von Nägeln (16), Riefelungen oder Unebenheiten.

21. Vorrichtung gemäß einem der Ansprüche 1 bis 20, wobei eine zur Sehne hin liegende Fläche (14) der Membran abgerundete Kanten (15) aufweist.

Revendications

1. Dispositif implantable dans le corps vivant, pour la fixation et le renforcement de tendons et/ou le renforcement d'os, comportant une membrane essentiellement plate (1; 10, 20) dont la forme externe est arrondie, comportant une surface faisant face au tendon ou à l'os et au moins deux perforations (2, 3; 4, 5; 12; 21, 22), ledit dispositif contenant uniquement un matériau polymérique résorbable ou dégradable choisi dans le groupe constitué de polyhydroxyacides, de polysaccharides, de polyamines, de polyaminoacides, de polyorthoesters, de polyanhydrides, de polyamidoesters, de polydioxanones, de polyesteramides, de copolyoxalates, de polycarbonates ou de poly-(glutamic-co-leucine), caractérisé en ce que
   A) ledit matériau polymérique est de qualité très pure;
   B) ledit matériau polymérique présente un module de Young dans la plage de 1 à 50 GPa;
   C) ledit matériau polymérique présente une résistance à la traction dans la plage de 0,1 à 20,0 GPa;
   D) au moins 90 pourcent en poids dudit matériau polymérique présente un poids moléculaire dans la plage de 200.000 à 400.000;
   E) ledit matériau polymérique présente une polydispersion dans la plage de 1,2 à 100,0; et
   F) les chaînes polymériques dudit matériau polymérique sont au moins partiellement orientées.

2. Dispositif selon la revendication 1, dans lequel ladite membrane contient de plus un matériau polymérique-céramique résorbable ou dégradable.

3. Dispositif selon la revendication 1 ou 2, dans lequel ledit matériau polymérique et/ou ledit matériau polymérique-céramique résorbables ou dégradables présentent une structure non poreuse.

4. Dispositif selon la revendication 1 ou 2, dans lequel ledit matériau polymérique et/ou ledit matériau polymérique-céramique résorbables ou dégradables présentent une structure poreuse, avec une porosité réglée dans la plage de 0,05 à 200 µm, de préférence dans la plage de 0,2 à 5,0 µm.

5. Dispositif selon l'une quelconque des revendications 1 à 4, dans lequel ladite membrane présente une forme externe circulaire.

6. Dispositif selon l'une quelconque des revendications 1 à 4, dans lequel ladite membrane présente la forme d'un ruban à extrémités arrondies, avec au moins deux perforations à chacune des deux extrémités.

7. Dispositif selon l'une quelconque des revendications 1 à 6, dans lequel ladite membrane est déformable pour s'adapter à la forme d'un os.

8. Dispositif selon l'une quelconque des revendications 1 à 7, dans lequel l'épaisseur de ladite membrane est située entre 0,5 et 6,0 mm.

9. Dispositif selon la revendication 8, dans lequel l'épaisseur de ladite membrane est située entre 1,0 et 2,0 mm, de préférence entre 1,4 et 1,5 mm.

10. Dispositif selon l'une quelconque des revendications 1 à 9, dans lequel ledit module de Young est dans la plage de 5 à 15 GPa, de préférence dans la plage de 7 à 10 GPa.

11. Dispositif selon l'une quelconque des revendications 1 à 10, dans lequel ladite résistance à la traction est dans la plage de 0,5 à 3,0 GPa, de préférence dans la plage de 0,7 à 2,5 GPa.

12. Dispositif selon l'une quelconque des revendications 1 à 11, dans lequel au moins 90 pourcent en poids dudit matériau polymérique présentent un poids moléculaire dans la plage de 300.000 à 350.000.

13. Dispositif selon l'une quelconque des revendications 1 à 12, dans lequel ledit matériau polymérique présente une polydispersion dans la plage de 1,5 à 3,0.

14. Dispositif selon l'une quelconque des revendications 1 à 13, dans lequel lesdits polyhydroxyacides comprennent le polycaprolactone, le poly(L-lactide), le poly(DL-lactide), le polyglycolide, le poly(DL-lactide-co-glycolide),la poly (DL-lactide-co-caprolactone).

15. Dispositif selon l'une quelconque des revendications 1 à 14, dans lequel un agent d'activation des fibroblastes est incorporé dans la matrice polymérique.

16. Dispositif selon l'une quelconque des revendications 1 à 14, dans lequel un agent d'ostéoplasie est incorporé dans la matrice polymérique.

17. Dispositif selon l'une quelconque des revendications 1 à 14, dans lequel un agent antibiotique est incorporé dans la matrice polymérique.

18. Dispositif selon l'une quelconque des revendications 1 à 17, dans lequel le matériau polymérique présente un taux de dégradation in situ dans la plage de 6 à 24 mois.

19. Dispositif selon l'une quelconque des revendications 1 à 18, dans lequel ladite membrane est préformée pour s'adapter à la courbure de la tête humérale.

20. Dispositif selon l'une quelconque des revendications 1 à 19, dans lequel une surface (14) de ladite membrane faisant face au tendon et/ou à l'os est pourvue d'une structure tridimensionnelle, de préférence sous la forme de pointes (16), d'ondulations ou d'irrégularités.

21. Dispositif selon l'une quelconque des revendications 1 à 20, dans lequel une surface (14) de ladite membrane faisant face au tendon est pourvue de bords arrondis (15).

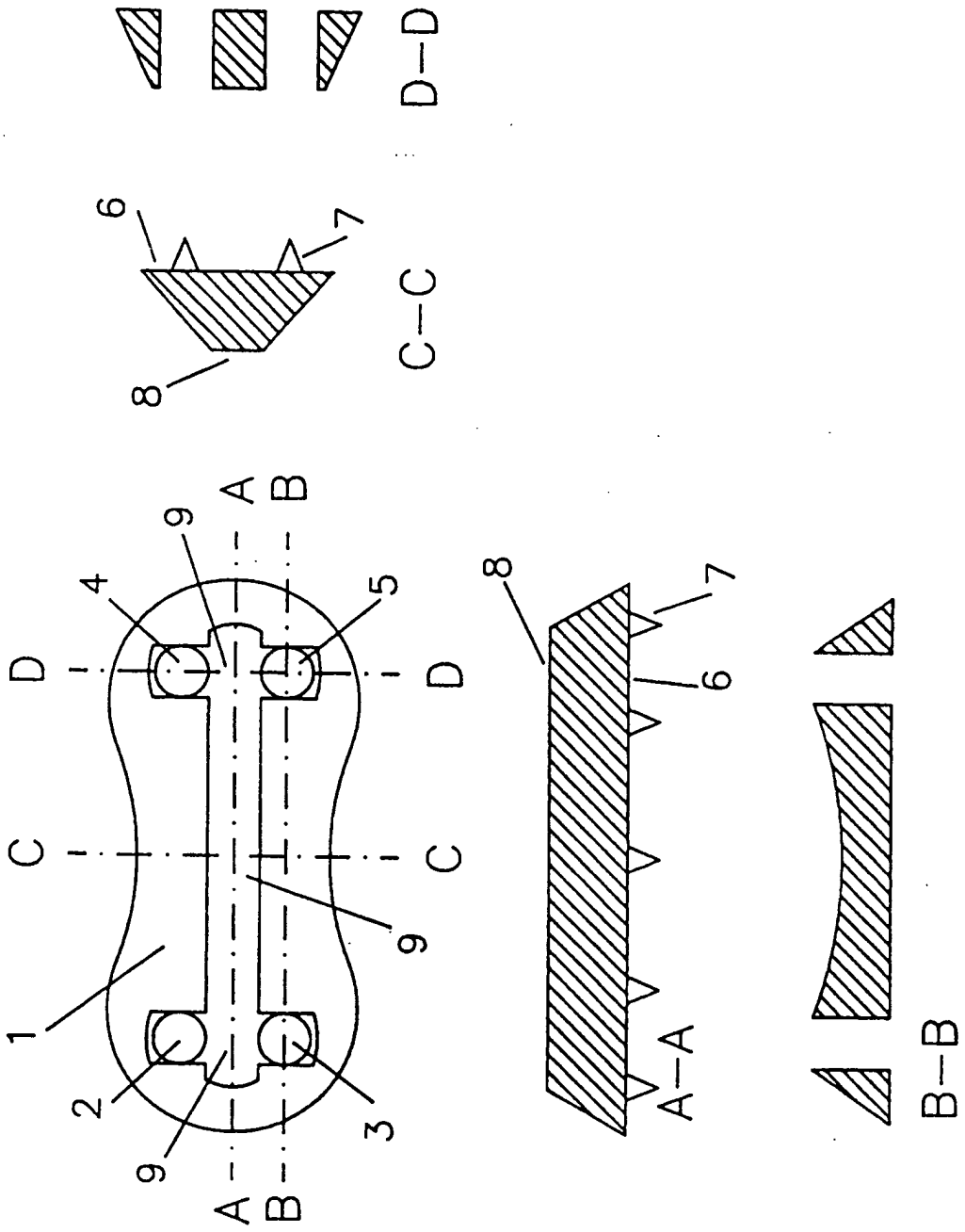

Fig.1

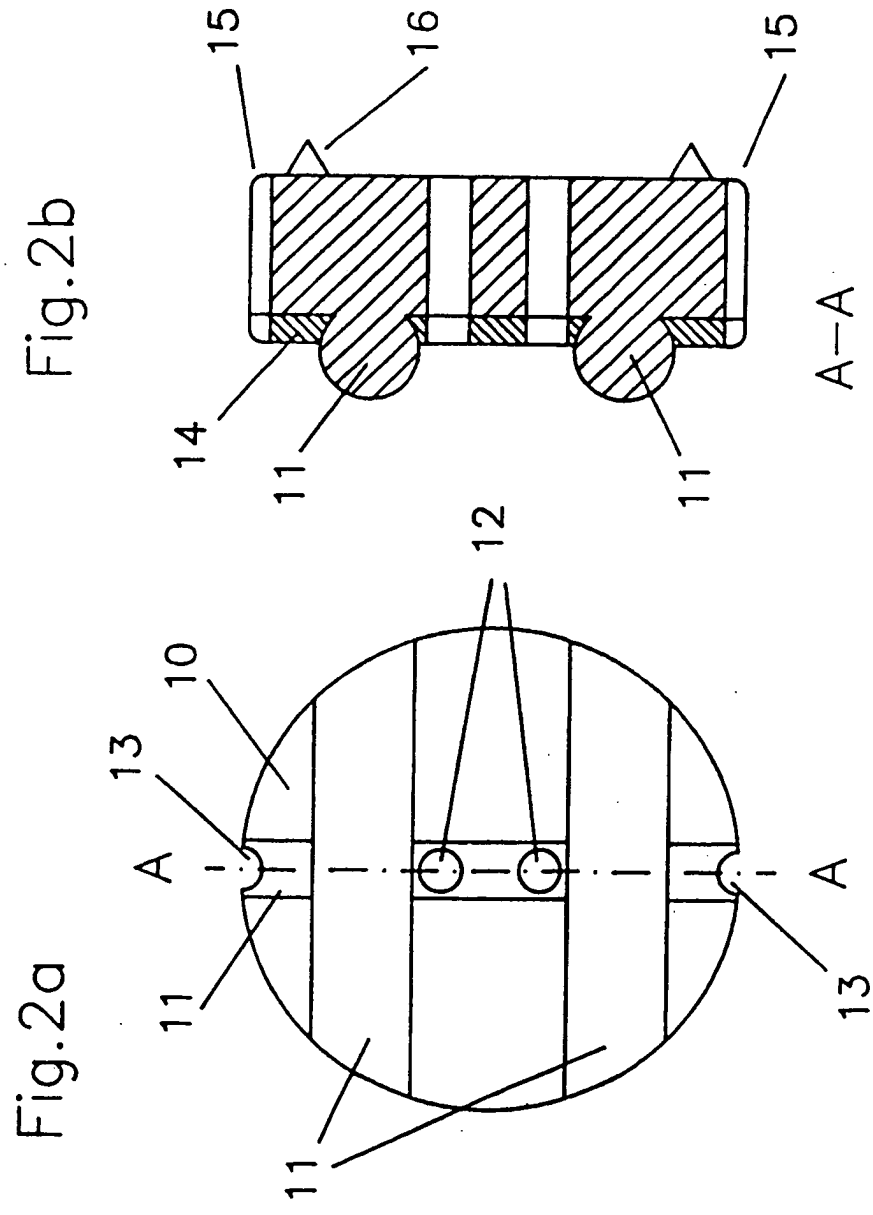
Fig.2a
13
10
A
A
11
12
11
13
Fig.2b
15
16
15
14
11
11
A–A
Fig.2c
13
10
11
12
11
13

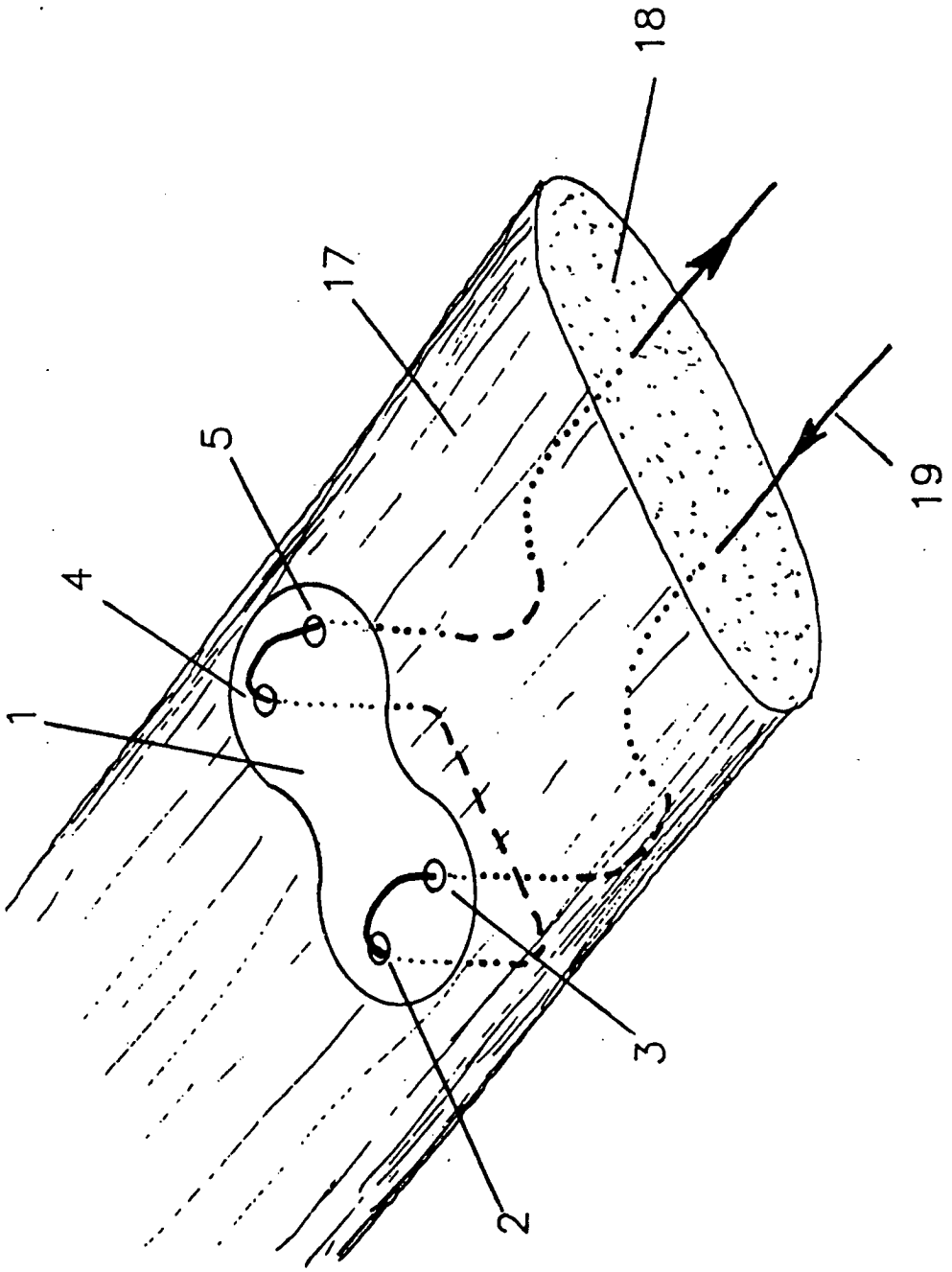

Fig.3

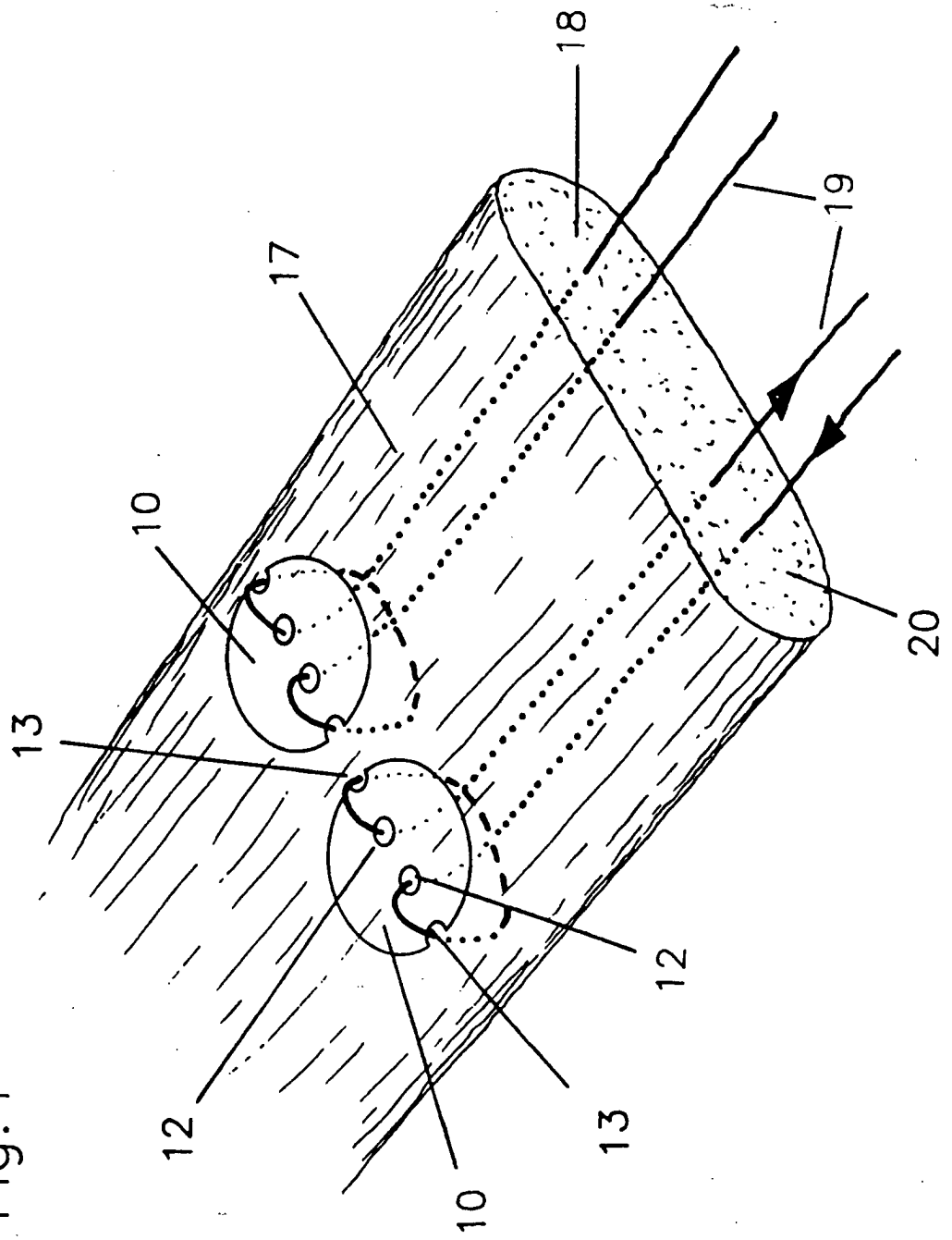

Fig.4

Fig.5

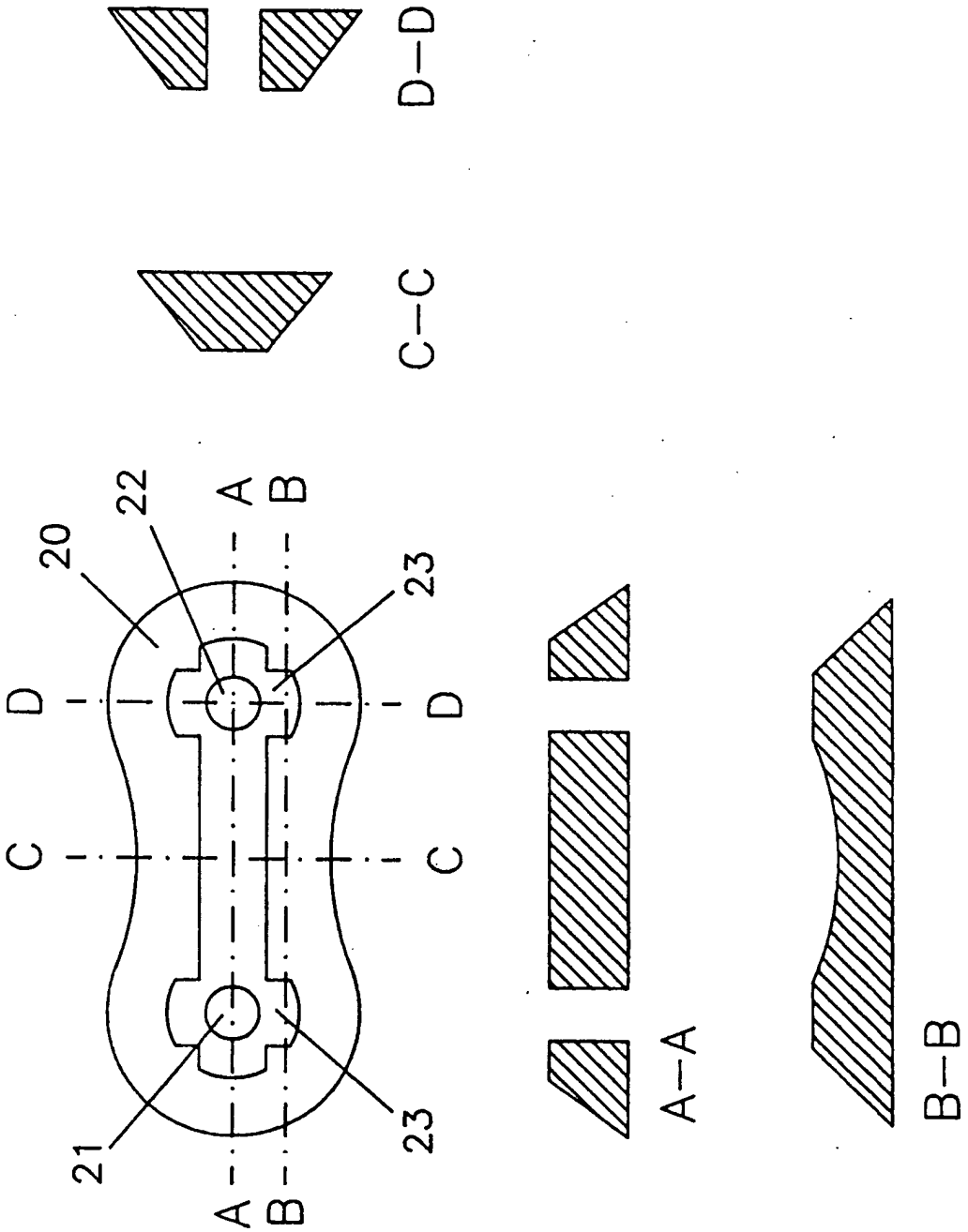

Fig.6